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** USTR B A C K G R O U N D P A P E R **

TRIPs and Health Emergencies

- The United States is committed to working with countries around the world to end the scourge of tragic pandemics such as HIV/AIDS, malaria and tuberculosis.

- The United States understands the urgent need for affordable access to critical medicines that will help countries deal with such health emergencies.

- The United States is pursuing a comprehensive, integrated approach to pandemics such as HIV/AIDS, stressing education, prevention, care, training, and treatment.

- The United States supports a strong declaration in Doha affirming the right of each WTO Member to use those provisions of the TRIPs Agreement providing flexibility to help deal with tragic pandemics, such as HIV/AIDS, malaria, and tuberculosis, or other circumstances of extreme urgency. We also support affirming that TRIPs contains crucial pharmaceutical-related patent protections – providing necessary incentives for continued research and development.

- The United States has proposed a statement in Doha declaring that all WTO countries, regardless of their level of development, may make full use of the flexibilities provided for by the TRIPs Agreement – including "compulsory licenses" and "parallel importing" – to address health crises.

    - Under "compulsory licensing," a government conditionally authorizes third parties (or the government itself) to use a patented product without the authorization of the patent holder.

  - Under "parallel importing," authentic patented products are imported into a country without the authorization of the patent holder.

- We support clarifying the flexibility in the TRIPs Agreement. As Gro Harlem Brundtland, the Director-General of the World Health Organization, said recently, "Clarity on this flexibility would allow [WTO] members to formulate public health policies in ways that do not infringe on the rights of patent holders.

- The United States opposes a declaration that creates a broad carve-out to TRIPs ostensibly to "protect public health." Instead of permitting targeted exceptions to TRIPs, this open-ended language would result in commonplace erosion of patent protections – from pharmaceuticals to medical software – and thwart research into medicines to treat life-threatening diseases. Indeed, it could subvert the entire TRIPs Agreement.

- The United States has proposed granting least-developed countries a 10-year extension, to 2016, to come into full compliance with all pharmaceutical-related patent obligations under TRIPs. This will give them the assurance that they will not be challenged in the WTO as they take steps to address HIV/AIDS and other pandemics.

- The United States has also proposed a moratorium of at least five years on WTO challenges to the actions of sub-Saharan African developing nations as they respond to HIV/AIDS, infections related to AIDS, and other health crises, such as malaria and tuberculosis.

TRIPs (general)

- The TRIPs Agreement strikes an appropriate balance between offering incentives for innovation and ensuring that there is access to medicines.

- The strong patent protection embedded in TRIPs is a fundamental element of the global health-care system. Patent systems stimulate research, development and distribution of safe and effective drugs that are used to prevent, treat, and cure illnesses.

- As United Nations Secretary-General Kofi Annan pointed out in April, "Intellectual property protection is key to bringing forward new medicines, vaccines, and diagnostics urgently needed for the health of the world's poorest people. The United Nations fully supports the TRIPs agreement – including the safeguards incorporated within it."

- And as WHO Director-General Brundtland said recently, "Continuing innovation is essential: This requires both incentives to invest in research on the diseases that drive poverty and

protection provided by international agreements on intellectual property."

- TRIPs is just one element of the needed global response to a pandemic such as HIV/AIDS. The United States is pursuing a comprehensive, integrated approach, stressing education, prevention, care, training, and treatment.

    - The United States is the largest bilateral donor of funds for HIV/AIDS assistance, providing over $2 billion per year on related research, much of which helps to address developing country problems. This represents nearly 50 percent of all international HIV/AIDS funding. We were the first contributor, and remain the largest, at $200 million, toward the international "Global Fund to Fight AIDS, TB and Malaria."

- A period of market exclusivity for innovated products and processes is essential to ensure development of new health care products.

- Without the economic incentives provided by patent protections, and the expectation of market exclusivity, the private sector will be unable to take the risks associated with research and development of new health-care products. And the supply of new drugs, for the treatment and cure of life-threatening diseases, would contract.

    - New drugs often cost between $250 million and $500 million to develop, and involve more than a decade of research

    - Companies invest billions of dollars annually on thousands of ideas, but only a small percentage ever come to market and prove commercially successful.

    - Such invention and creation is undermined when competitors, who bear none of the costs of unsuccessful research, are able to copy research-based products and undercut their investment.

- Strong, effective intellectual property protection is the cornerstone on which an attractive investment climate is built, and produces long-run economic benefits.

    - Provides incentives for innovation by helping to create an environment in which innovation is rewarded.

    - Encourages development of lower cost methods of production and distribution of existing products.

    - Invites introduction of new, safe and effective products, technology and services.

- Stimulates development of in-country markets through the adaptation and improvement of existing products and technology.

- Under the current patent system, extensive medical research is being carried out.
  - In the United States alone, there are more than 100 new drugs for the treatment of HIV/AIDS in development, 120 new drugs to treat heart disease and stroke, 135 drugs to treat and prevent infectious diseases, 400 new drugs for treating or curing various forms of cancer, and 700 new drugs to address diseases associated with aging.

- A strong IPR regime has additional benefits.
  - It helps attract foreign direct investment; companies will be more willing to invest in countries secure in the knowledge that there is a legal structure to protect their innovations from unauthorized copying.
  - It discourages brain drain, encouraging the best and the brightest in developing nations to carry out their research at home, knowing the fruits of their labors will enjoy patent protections.

Cipro

- Health and Human Services Secretary Tommy Thompson negotiated with Bayer the per-tablet price at which the federal government would purchase Cipro. His actions were fully consistent with the international agreements to which the United States is a party.
  - Contrary to media reports, Secretary Thompson never threatened to break Bayer's patent.
  - He stated, publicly, that if he or the Congress had contemplated breaking the patent, compensation would have to be paid to the patent owner (Bayer), as required by TRIPS.

- The TRIPs Agreement contains flexibilities that can be utilized in times of crisis or emergency. Given the discovery of anthrax in New York, Florida, and the Washington, DC metropolitan area, and the risk of individuals being infected with a potentially deadly virus, the United States *would* be permitted under TRIPs to exercise its rights to go outside the patent process. Moreover, U.S. law entitles patent holders to seek "reasonable and entire compensation" in the event of non-commercial use of their patents by the U.S. Government.

- These flexibilities are not limited to the United States. They are available to every other member of the WTO.

Canada

- The compromise agreement on the purchase of Cipro involving the Canadian government, Bayer, and a generic drug producer does not appear to violate the TRIPs Agreement.

- The Canadian health authorities are acquiring Cipro exclusively from Bayer during the period of patent protection.

- The compromise is an improvement over the Canadian government's original action, which would have involved the purchase of Cipro with no involvement from Bayer.

- The Canadian experience illustrates how easily public pressure can build for prompt governmental responses to health issues. Fortunately, the Canadian government recognized that acting within TRIPs rules was the most sensible and effective response.

Evolution of USG Policy

- 9/17/99: Clinton administration drops its demands that South Africa ease parts of a pharmaceutical-import law, dealing with compulsory licensing and parallel importing. This law had earlier prompted a legal challenge by American and international pharmaceutical companies.

- 12/1/99: The Clinton administration announces its intention to develop a "cooperative approach" on IPR health issues to ensure that U.S. trade laws remain sufficiently flexible to respond to "legitimate public health crises" throughout the world. South Africa removed from the special 301 "watch list." South Africa had been placed on the list because of its policies on compulsory licensing and parallel imports were seen as conflicting with TRIPs.

- 5/10/00: President Clinton issues an executive order pledging that the United States "shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy" of sub-Saharan Africa countries, as long as these laws or policies promote access to drugs to treat HIV/AIDS and are consistent with the TRIPs Agreement. Effect is to hold these countries to only a TRIPs standard, not a TRIPs-plus standard.

- 2/22/01: USTR issues the following statement: "The HIV/AIDS crisis is a terrible tragedy for countries, families and individuals. USTR is not considering a change in the present flexible

policy: Consistent with our overall effort to protect America's investment in intellectual property, USTR will seek to contribute to Administration efforts to work with countries that develop serious programs to prevent and treat this horrible disease."

- 6/25/01: USTR announces that the United States and Brazil have agreed to transfer their disagreement over a provision of Brazil's patent law from formal WTO litigation to a newly created bilateral consultative mechanism (the provision is designed to pressure patent owners to manufacture their invention in Brazil). The consultative mechanism permits more effective, and less confrontational, consideration of intellectual property issues and ensures that such discussions do not divert attention away from the shared goal of combating the spread of HIV/AIDS.

- 10/13/01: USTR proposes at Singapore Ministerial that at Doha Ministers agree to extend the TRIPs transition period regarding pharmaceuticals for all least-developed countries and commit to a dispute settlement moratorium for sub-Saharan African developing countries on measures to address pandemics such as HIV/AIDS.

Note: Since December 1999, U.S. policy has been to apply no higher standard than the TRIPs Agreement in situations where foreign governments are trying to address health crises. The policy has not been limited to any region.

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